

ASSEMBLY BILL

No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

An act to amend Sections 4037 and 4051 of, to add Section 4019.5 to, to repeal Section 4033 of, and to repeal and add Section 4123 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 595, as introduced, Negrete McLeod. Pharmacy: compounding of prescription drugs.

The Pharmacy Law provides for the licensing and regulation of pharmacists and associated persons by the California State Board of Pharmacy. A violation of the law is a crime.

This bill would define compounding of a prescription drug for the purposes of that law and would make other related changes in that regard. Because this bill would revise the definition of a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4019.5 is added to the Business and Professions Code, to read:

4019.5. (a) “Compounding” means any of the following activities occurring in a pharmacy pursuant to a prescription:

(1) Altering the dosage form, flavor, or delivery system of a drug.

(2) Altering the strength of a drug.

(3) Combining components or active ingredients.

(4) Preparing a drug product from bulk chemicals.

(b) “Compounding” shall not include the reconstitution of a drug pursuant to the manufacturer’s direction for oral, rectal, or topical administration.

SEC. 2. Section 4033 of the Business and Professions Code is repealed.

~~4033. (a) “Manufacturer” means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.~~

~~(b) Notwithstanding subdivision (a), “manufacturer” shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.~~

~~(c) Notwithstanding subdivision (a), “manufacturer” shall not mean a pharmacy that, at a patient’s request, repackages a drug previously dispensed to the patient, or to the patient’s agent, pursuant to a prescription.~~

SEC. 3. Section 4037 of the Business and Professions Code is amended to read:

4037. (a) “Pharmacy” means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where ~~prescriptions are compounded~~ *dangerous drugs and dangerous devices are stored*. “Pharmacy” includes, but is not limited to, any area, place, or premises ~~described in a~~

1 ~~license issued~~ *licensed* by the board wherein controlled
2 substances, dangerous drugs, or dangerous devices are stored,
3 possessed, prepared, ~~manufactured~~, derived, compounded, ~~or~~
4 repackaged, ~~and from which the controlled substances, dangerous~~
5 ~~drugs, or dangerous devices are furnished, sold, or dispensed at~~
6 retail.

7 (b) "Pharmacy" shall not include any area in a facility licensed
8 by the State Department of Health Services where floor supplies,
9 ward supplies, operating room supplies, or emergency room
10 supplies of dangerous drugs or dangerous devices are stored or
11 possessed solely for treatment of patients registered for treatment
12 in the facility or for treatment of patients receiving emergency
13 care in the facility.

14 SEC. 4. Section 4051 of the Business and Professions Code is
15 amended to read:

16 4051. (a) Except as otherwise provided in this chapter, it is
17 unlawful for any person to ~~manufacture~~, compound, furnish, sell,
18 or dispense any dangerous drug or dangerous device, or to
19 dispense or compound any prescription pursuant to Section 4040
20 of a prescriber unless he or she is a pharmacist under this chapter.

21 (b) Notwithstanding any other law, a pharmacist may
22 authorize the initiation of a prescription, pursuant to Section
23 4052, and otherwise provide clinical advice or information or
24 patient consultation if all of the following conditions are met:

25 (1) The clinical advice or information or patient consultation is
26 provided to a health care professional or to a patient.

27 (2) The pharmacist has access to prescription, patient profile,
28 or other relevant medical information for purposes of patient and
29 clinical consultation and advice.

30 (3) Access to the information described in paragraph (2) is
31 secure from unauthorized access and use.

32 SEC. 5. Section 4123 of the Business and Professions Code is
33 repealed.

34 ~~4123. Any pharmacy that contracts to compound a drug for~~
35 ~~parenteral therapy, pursuant to a prescription, for delivery to~~
36 ~~another pharmacy shall report that contractual arrangement to the~~
37 ~~board. That information shall be reported by the pharmacy~~
38 ~~performing the compounding services within 30 days of~~
39 ~~commencing that compounding.~~

1 SEC. 6. Section 4123 is added to the Business and Professions
2 Code, to read:

3 4123. (a) A compounded drug product shall only be
4 dispensed or furnished to a patient pursuant to a prescription
5 meeting the requirements of Section 4040.

6 (b) A compounded drug product shall only be dispensed or
7 furnished to a patient where the prescription has been generated
8 solely within an established professional relationship between the
9 prescriber, patient, and dispensing pharmacy.

10 (c) A pharmacy may conduct anticipatory compounding of a
11 drug product in limited quantity, as defined by regulation of the
12 board, before receipt of a prescription order for that drug product,
13 where the quantity of each drug product compounded in
14 anticipation of receipt of prescription orders is based on a
15 documented history of receipt of prescription orders generated
16 solely within an established professional relationship between
17 prescribers, patients of the pharmacy, and the pharmacy.

18 (d) A pharmacy may contract with another pharmacy to
19 compound drug products on behalf of its patients.

20 (e) A pharmacy may only base its anticipatory compounding
21 on a documented history of prescription orders received for its
22 own patients or customers, and not those patients or customers of
23 pharmacies with which it has a contractual relationship.

24 (f) Notwithstanding any other provision of this chapter, a
25 pharmacist may do both of the following:

26 (1) Compound a drug product pursuant to a prescription, for
27 delivery to another pharmacy pursuant to a contract for the
28 purpose of dispensing or furnishing the drug product to the
29 patient named in the prescription, provided that the drug is not
30 compounded prior to the receipt of the prescription.

31 (2) Repackage a drug previously dispensed to the patient at the
32 request of the patient or the patient's agent.

33 SEC. 7. No reimbursement is required by this act pursuant to
34 Section 6 of Article XIII B of the California Constitution because
35 the only costs that may be incurred by a local agency or school
36 district will be incurred because this act creates a new crime or
37 infraction, eliminates a crime or infraction, or changes the
38 penalty for a crime or infraction, within the meaning of Section
39 17556 of the Government Code, or changes the definition of a

- 1 crime within the meaning of Section 6 of Article XIII B of the
- 2 California Constitution.

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